BRIDGES | www.ictsd.org | Year 8 No.6 June 2004 | pages 3 and 4
Published by the International Centre for Trade and Sustainable Development

http://www.ictsd.org/monthly/bridges/BRIDGES8-6.pdf

Comment - Make Drugs Affordable: Replace TRIPs-plus by R&D-plus

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The global trade framework for financing new medical technologies is in trouble. It will and should change. If we want innovation, fairness and efficiency, we will need innovation in the trade framework.

In November 2001, WTO Members adopted the Doha Declaration on TRIPs and Public Health, which said the TRIPs Agreement "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all." This was a symbolic step toward fairness. But within months the US government launched a plethora of bilateral trade negotiations seeking tough new 'TRIPs-plus' intellectual property measures1 that would plainly undermine the declaration.

The European Commission, the United States and Japan have also raised issues concerning drug pricing in various bilateral trade discussions. In 1999, the European Commission2 and the US3 asked Korea to accept hefty prices for patented medicines. The European Commission brought a similar case against Turkey in 2003.4 The United States has a long history of attacking price control mechanisms in poor countries, and has recently launched a campaign to undermine price negotiations by higher income countries as well.5

Trade agreements involving intellectual property rights (IPRs) or drug prices are justified because of the need to provide incentives for research and development (R&D). For those who want medicines to be more affordable, it is necessary to confront the big issue of how we finance R&D on new products and provide equitable access.

The TRIPs Agreement and the growing number of new TRIPs-plus trade agreements are flawed. They seek to increase investment in R&D, but only by increasing prices. The more successful these agreements are in raising prices, the greater the problems of access. The conflict is most clear in developing countries, where patent owners sell to the highest income groups to maximise profits.6 But high-income countries are also increasingly rationing medicines. For instance, Singulair, a product to manage chronic asthma, is reimbursed in only some high-income countries. Drugs that treat severe illnesses come with astronomical price tags. According Dr Robert Wittes, a research scientist and former BMS executive, insurance companies are resisting paying for cancer drugs like Erbitux, which is priced at US$10,000 per month. 7 Wittes notes: "The increasing co-pay percentages of most plans and the capping of benefits in others will compel a major financial outlay for those determined to have the treatments." Third party payers will decide that medicines are simply not worth paying for, or limit 'off-label' uses – something that is particularly disturbing in cancer, where drugs are commonly used "for a broader array of indications than specifically approved by the FDA."

Marketing monopolies are also inefficient. Only a small fraction of the high prices is reinvested in research and development, and most of this on non-innovative 'me too' products for chronic diseases

that afflict high-income patients. Very little private R&D is invested in basic research, public goods such as the Human Genome Project (HGP) or Medline, the development of vaccines, or higher priority medicines, such as new treatments for malaria. Higher IPR protection for products is also associated with a number of other problems, including excessive secrecy and anti-competitive barriers to follow-on innovation.8

The massive investments in marketing medicines protected by patents and other exclusive rights are not only wasteful, they are also often associated with inappropriate use of products arising from fraudulent or unethical practices that skew the evidence and incentives that determine which medicines are prescribed.9

A framework that relies upon private marketing monopolies is morally repugnant, economically inefficient and corrupt. We can and should do better.

R&D-plus and Free Riding

We propose a new trade framework – focused directly on R&D rather than patent rights or drug prices, which are mechanisms to finance R&D.10 The idea is to change the context from commerce to health. This is not to say that money is not important. The development of new medicines is expensive. We need a global framework to ensure that the burden of paying for R&D is fairly shared. The trade framework has to prevent 'free riding'.

Agreements on IPRs or drug prices are partial steps to address free riding, but they only address one financing mechanism – high drug prices. There are other options. Countries can impose R&D mandates on private firms, such as requirements that a percentage of drug sales or insurance premiums be invested in R&D. Mechanisms like the US 'orphan drug' tax credit provide decentralised funding for clinical trials, as do tax incentives to donate money to charitable trusts, such as the Gates, Ford or Rockefeller Foundations. There is also the option of direct R&D funding via the public sector, such as the US$100 per capita US taxpayers spend for the National Institutes of Health (NIH). Some economists and political leaders are advocating greater use of public or private sector funded 'prizes' as a reward for successful innovation.

To sum up, while other countries spend less (per capita) on public sector R&D than the US does, they all do something, and there is growing interest in alternative mechanisms to finance R&D, such as public private partnerships (PPPs), tax breaks, research mandates, competitive intermediaries, or prize funds. These also cost money.

A trade framework that only recognises IPRs skews global investments, and forces us to choose high drug prices to finance new medicines. It does nothing to address free riding in public goods.

The R&D-plus approach would count both public and private expenditures. It would also allow countries the freedom to choose the optimal mix of public and private sector spending, and it would allow more flexibility in terms of finance mechanisms. Most importantly, it would allow countries to choose mechanisms that are consistent with desired levels of access, and which are more efficient in promoting useful innovation. Competition among financing mechanisms would be encouraged.

In an ambitious multilateral setting, the R&D-plus approach would involve setting research and development targets that would be reasonably related to incomes and stages of development of the country – such as 10 to 15 basis points of GDP. In meeting the targets, countries could buy high priced drugs from foreign pharmaceutical companies, like they do now, and get credit for the share of sales the

foreign firm actually reinvests in R&D. But countries could also choose other options, such as investing money in their own universities or businesses, using resources domestically to build capacity and provide skills and jobs.

For bilateral, regional or more limited multilateral negotiations, the R&D-plus approach can supplement or co-exist with traditional IPR agreements. In its free trade area negotiations with the US, Thailand could propose to increase domestic spending on research and development for SARS, Bird Flu or AIDS vaccines, in return for a weaker IPR chapter than the one in the Central American Free Trade Agreement (CAFTA).

More Thai spending on R&D for global infectious diseases would be attractive to many in the US Congress who want broader sharing of global R&D costs. It would also be a more attractive alternative for Thailand than facing high prices for drugs for heart disease or cancer that few would afford. R&D-plus would be a better outcome than TRIPs-plus for both the United States and Thailand.

For a number of reasons, R&D-plus is likely to lead to a more decentralised R&D infrastructure, with more technology transfer and capacity building than is likely for a TRIPs-plus approach.

R&D-plus, Health and Development Objectives

With TRIPs-plus we get too much investment in non-innovative copycat products, and too little investment in public goods, innovative medicines, vaccines and other health priorities. How would R&D-plus be better? Once the context of the trade agreement is changed from commerce to health, it easier to address social agendas. One mechanism is to provide for social weights that would increase the measured contribution toward benchmarks. Discussions of R&D treaties have focused on three areas where this might be useful:

- technology transfer: such as collaborative projects between higher and lower income countries;
- openness: such as the Human Genome Project (HGP), or open source drug development projects; and
- public health priorities: such as research on malaria and other neglected diseases or vaccines for AIDS and SARS.

Concluding Remarks

In this short article we have presented a trade framework that does not require a choice between access and innovation. It does not choose between private or public sector approaches. Both are likely to be used. R&D-plus is flexible, featuring decentralised decision-making. In its pure form, global negotiators decide on targets for floors on R&D funding. Social objectives are addressed through weights that increase measured contributions toward the targets. Each country then chooses how it will meet those targets. Some will choose stronger IPRs, while others will prefer open source approaches. Some will favour public sector management of investments, while others will rely upon a more entrepreneurial private (profit or non-profit) approach. Most will choose mixed approaches. In the short run, more incremental R&D-plus approaches can be used to avoid the worst aspects of TRIPs-plus agreements.

We believe R&D-plus is both feasible and likely. The current system is not working for developing countries or for high-income countries. Strong IPR models are imploding even in the United States and Europe. We must find ways to avoid the rationing, the costly inefficiencies and the corruption of the scientific and medical professions – and to promote more open science in order to promote greater innovation. R&D-plus is the future, but we need it now.

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ENDNOTES

1. For patents: limitations on compulsory licensing, extension of terms, broader patent scope and lower novelty standards, and linkage to drug registration. Also, exclusive rights in health registration data.
2. 1999/C 218/03. Rambau Garikipati, "EU companies frustrated with drug pricing guidelines," Korea Herald, 12 June 2004.
3. The Korean Government agreed in 1999 to price new, innovative drugs at the average price in the US, the UK, Germany, France, Italy, Switzerland and Japan. 2002 National Trade Estimate Report on Foreign Trade Barriers, USTR.
4. 2003/C 311/04.
5. The US introduced oversight of the Australia Pharmaceutical Benefits Scheme (PBS) into the US/Australia FTA. Also, International Trade Administration, Drug Pricing Study Federal Register: June 1, 2004, Volume 69, Number 105, page 30882-30883.
6. In the Dominican Republic, the price of the heart disease drug Plavix is 60 percent of the income of an unskilled worker. Until recently, AIDS drugs in developing countries were priced at more than US$10,000 per year.
7. Robert E. Wittes, "Cancer Weapons, Out of Reach," Washington Post, June 15, 2004.
8. Keeping science open: the effects of intellectual property policy on the conduct of science. Royal Society. April 2003.
9. Richard Smith, "Medical journals and pharmaceutical companies: uneasy bedfellows, BMJ 2003;326:1202-1205 (31 May).
10. TJ Hubbard and J Love. "A New Trade Framework for Global Healthcare R&D" PLoS Biology, 2004. 2(2): p147-150.

CPTech web page on trade framework for R&D